

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

FRESENIUS MEDICAL CARE
HOLDINGS, INC., et al.,

No. C 03-1431 SBA

Plaintiffs,

ORDER

v.

[Docket No. 498]

BAXTER INTERNATIONAL, INC., et al.,

Defendants.

This matter comes before the Court on Defendants Baxter International, Inc. and Baxter Healthcare Corporation's (collectively, "Defendants" or "Baxter") Motion to Strike Exhibits 1 and 13 to Fresenius' Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent Nos. 5,326,476 and 5,744,027. Having read and considered the arguments presented by the parties in the papers submitted to the Court, the Court finds this matter appropriate for resolution without a hearing. The Court hereby DENIES Baxter's Motion to Strike Exhibits 1 and 13 to Fresenius' Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent Nos. 5,326,476 and 5,744,027 [Docket No. 498].

BACKGROUND

Plaintiffs and counter-defendants Fresenius USA, Inc. and Fresenius Medical Care Holdings, Inc. (collectively "Fresenius") initiated this patent suit on April 4, 2003 by filing a Complaint for Declaratory Judgment of Non-infringement and Invalidity against defendants and counter-plaintiffs Baxter International, Inc. and Baxter Healthcare Corporation (collectively "Baxter"). Fresenius cited five patents in its complaint: (1) U.S. Patent No. 5,247,434 ("434 Patent"); (2) U.S. Patent No.

5,326,476 ("476 Patent"); (3) U.S. Patent No. 6,284,131 B1 ("131 Patent"); (4) U.S. Patent No. 5,486,286 ("286 Patent"); and (5) U.S. Patent No. 5,744,027 ("027 Patent") (collectively "patents-in-suit").

On May 14, 2003, Baxter answered and counterclaimed that Fresenius' 2008H and/or 2008K hemodialysis machines infringe four of the five patents. On October 20, 2003, Baxter amended its answer and counterclaims to assert infringement of the '286 Patent.

On February 21, 2006, Fresenius filed a Motion for Summary Judgment seeking partial summary judgment that the asserted claims of the '434 and '131 patents are invalid as obvious under U.S.C. § 103(a); that the asserted claims of the '131 patent are invalid as anticipated under 35 U.S.C. § 102(b); and that certain asserted claims of the patents-in-suit are invalid for failure to satisfy the enablement and best mode requirements of 35 U.S.C. § 112.

Also on February 21, 2006, Fresenius filed a Motion for Summary Judgment seeking partial summary judgment that claim 5 of the '476 Patent and claim 11 of the '027 Patent are invalid as obvious under 35 U.S.C. § 103(a); that claim 7 of the '476 Patent and claims 1, 2, 4, 6-8, 10, and 12-16 of the '027 Patent are invalid as anticipated under 35 U.S.C. § 102(b); and that claim 5 of the '476 Patent is invalid for failure to satisfy the definiteness and enablement requirements of 35 U.S.C. § 112.

On March 7, 2006, Baxter filed a Motion for Partial Summary Judgment of Validity seeking judgment that the asserted claims of the '434 and '131 patents are not invalid under 35 U.S.C. § 102 for anticipation, and that certain asserted claims of the patents-in-suit are not invalid for violating the best mode and/or enablement requirements of 35 U.S.C. § 112.

On March 21, 2006, Baxter filed the instant Motion to Strike Exhibits 1 and 13 to Fresenius' Motion for Summary Judgment of Invalidity of '476 and '026 Patents [Docket No. 498].

ANALYSIS

In the instant Motion to Strike, Baxter asserts two arguments: (1) that the "CMS-08 Handbook"¹ that Fresenius relies upon must be stricken because it has not been properly authenticated under Federal

¹The CMS-08 Handbook has been offered by Fresenius to support its assertion that the "CMS08/A2008D System" anticipates and renders obvious the asserted claims of the '476 Patent. The Handbook is attached as Exhibit 1 to the Declaration of Thomas S. McClenahan.

Rules of Evidence 604 and 901; and (2) that the Seratron Patient Recoding and Monitoring System ("PRSM") System Specification² that Fresenius relies upon must be stricken under Federal Rules of Evidence 803, 901, and 902 because it is unauthenticated, is hearsay, is not a business record, and lacks any indicia of trustworthiness. Having considered Baxter's arguments offered in support of its Motion to Strike, the Court hereby DENIES Baxter's Motion in its entirety. Each evidentiary objection is addressed separately below.

1. The CMS-08 Handbook

With respect to the CMS-08 Handbook (the "Handbook"), Baxter argues that the document is inadmissible because it appears to be an English translation of a German document that has not been properly authenticated by a qualified interpreter as a certified translation pursuant to Rule 901³ and 604.⁴ According to Baxter, before introducing this document into evidence, Fresenius was required to establish: (1) how the document was translated, (2) who translated it, and (3) the qualifications and expertise of the translator. *Kesel v. United States Parcel Service, Inc.*, 2002 WL 102606 at * 3 (N.D. Cal. 2002).

As Fresenius points out, however, Baxter's reliance on Rules 901 and 604 is misplaced. Rule 604, which pertains to interpreters, is inapplicable because the version of the CMS-08 Handbook that Fresenius relies upon *is not a translation*. Rather, Fresenius has shown that the Handbook referenced in its summary judgment briefing is an original English document created by Fresenius A.G. for use in English-speaking countries and provided by Fresenius USA in connection with the CMS-08. *See* Miller Decl. at Ex. A (Ward Depo. at 65:22-25). Baxter was aware of this fact before filing its Motion to

²The PRSM Specification has been offered by Fresenius in support of its assertion that the Seratron System anticipates and renders obvious the asserted claims of the '027 Patent. The Seratron System includes the Cordis Dow Seratron Dialysis Control System, the Seratron Modeling Programmer, and the Seratron Patient Recording System. The PRSM Specification is attached as Exhibit 13 to the Declaration of Thomas S. McClenahan.

³Rule 901 provides that "[t]he requirement of authentication or identification as a condition precedent to admissibility is satisfied by evidence sufficient to support a finding that the matter in question is what its proponent claims" Fed. R. Evid. 901.

⁴Rule 604 provides that "[a]n interpreter is subject to the provisions of [the Federal Rules of Evidence] relating to qualification as an expert and the administration of an oath or affirmation to make a true translation." Fed. R. Evid. 604.

1 Strike, as one of Fresenius' witnesses, Dr. Ward, testified to this fact on March 6, 2006. *Id.* As such,
2 Baxter's assertion that it was still confused about the status of the Handbook when it filed its belated
3 Motion to Strike on March 21, 2006 is disingenuous.

4 Moreover, the persuasiveness of Baxter's Motion is undermined considerably by the fact that the
5 authorities Baxter relies upon in urging this Court to strike the Handbook are all inapposite. Indeed, all
6 of the cases Baxter cites involve situations where the translation was created during the course of the
7 litigation and where the translator's certification was either missing or inadequate. *See, e.g., Jack v.*
8 *Trans World Airlines*, 854 F. Supp. 654, 659 (N.D. Cal. 1994) (excluding foreign language affidavits
9 due to translator's failure to properly certify the translation); *Kesel*, 2002 WL 102606 at * 3 (same); *Sun*
10 *v. Governmental Authorities on Taiwan*, 2001 WL 114443 at * 5 (N.D. Cal. 2001) (concurrently
11 admitting translated documents that were properly authenticated and striking deposition transcripts for
12 which 'no authenticated English translation was provided.'").

13 Baxter has not presented any other rational basis for this Court to exclude the Handbook as
14 inauthentic under Rule 901. *See* Fed. R. Evid. 901 (Authentication is satisfied "by evidence sufficient
15 to support a finding that the matter in question is what its proponent claims"); *Hal Roach Studios, Inc.*
16 *v. Richard Feiner & Co., Inc.*, 896 F.2d 1542, 1551 (9th Cir. 1990) ("A competent witness with personal
17 knowledge [can] authenticate a document."). In fact, it appears that the true basis for Baxter's Motion
18 to Strike is its contention that Fresenius has not shown that the Handbook was ever "printed, used,
19 and/or distributed in the United States or anywhere." However, this is a legal argument going to the
20 merits of Fresenius' invalidity claim – not an evidentiary objection – and therefore is not a proper basis
21 for excluding the document outright under the Federal Rules of Evidence. Accordingly, Baxter's Motion
22 to Strike the CMS-08 Handbook is DENIED.

23 2. PRSM Specification

24 Baxter next argues that the PRSM Specification is inadmissible because it was found in the
25 garage of an "interested" witness, is undated, appears incomplete, and was not maintained or kept in the
26 ordinary course of business.

27 First and foremost, the Court notes that the manner in which Baxter attempts to characterize
28 Charles Ragsdale as an "interested" witness is unfounded. While it is undisputed that Mr. Ragsdale has

1 been retained by Fresenius to serve as an expert in this litigation, it is also undisputed that Mr. Ragsdale
2 is not otherwise employed by Fresenius. In fact, the Ragsdale Declaration clearly states that Mr.
3 Ragsdale was employed by Cordis Dow as a Manager in research electronics from 1979 to 1983.
4 *See* Ragsdale Decl. at ¶ 6. Moreover, Baxter's suggestion that Mr. Ragsdale has falsified or fabricated
5 evidence merely to aid Fresenius in the instant litigation – to which he is not a party – is nothing more
6 than bare and unsubstantiated innuendo and therefore is completely improper.

7 Baxter has also not persuasively shown that Fresenius has failed in its burden of properly
8 authenticating and admitting the PRSM Specification into evidence. In fact, the PRSM Specification
9 was authenticated by its author, Mr. Ragsdale, during his deposition. *See* Fed. R. Evid. 901; *Hal Roach*
10 *Studios, Inc.*, 896 F.2d at 1551; 31 Wright & Gold, *Federal Practice and Procedure: Evidence* § 7106,
11 43 (2000) ("A document can be authenticated [under Rule 901(b)(1)] by a witness who wrote it, signed
12 it, used it, or saw others do so.").

13 Additionally, the Court finds that the document also qualifies as authentic under Rule 901(b)(8).
14 Pursuant to Rule 901(b)(8), an "ancient" document is considered authentic if: (1) it is in such condition
15 as to create no suspicion concerning its authenticity; (2) it was in a place where it, if authentic, would
16 likely be; and (3) it has been in existence for twenty years or more. All of these factors are met here.
17 Specifically, Mr. Ragsdale has testified that the document was created no later than 1981 and that he
18 located the document in his personal files. *See* Gemmell Decl. ISO Mot. to Strike Exs. 1 and 13 at Ex.
19 C (Ragsdale Depo. at 171:7-19, 180:8-10). There is absolutely nothing about the condition of the
20 document that has been brought to the Court's attention that even suggests that the document is of a
21 suspicious origin.⁵ Because the PRSM Specification is authenticated under Rule 901(b)(8), it is
22 admissible under the Rule 803(16) exception to the hearsay rule. *See* Fed. R. Evid. 803(16)
23 ("Statements in a document in existence twenty years or more the authenticity of which is established"
24 are exceptions to the hearsay exclusion).

25
26 ⁵While Baxter argues that the document is suspicious because it is not accompanied by a
27 company "memorandum," Mr. Ragsdale explained in his deposition that such a memorandum would
28 not have been attached to the original document. *See* Gemmell Decl. ISO Mot. to Strike Exs. 1 and 13
at Ex. C (Ragsdale Depo. at 180:11-23). As such, the absence of a memorandum does not make the
document's authenticity questionable, as Baxter suggests.

Even if the "ancient document" hearsay exception did not apply, however, Fresenius has also shown that the PRSM Specification meets the "business record" hearsay exception. *See* Fed. R. Evid. 803(6). The "business record" exception to the general hearsay exclusion allows for the admission of records of a company's regularly conducted business. For a document to be admissible as a business record, the proponent must show that: (1) the document was made by a regularly conducted business activity; (2) the document was kept in the regular course of business; (3) it was the regular practice of that business to make the document; (4) and the document was made a person with knowledge or from information transmitted by a person with knowledge. *Clark v. City of Los Angeles*, 650 F.2d 1033, 1036-37 (9th Cir. 1981). Such foundational requirements must also be shown by the testimony of the company custodian or other qualified witness. *Tongil Co., Ltd. v. Vessel Hyundai Innovator*, 968 F.2d 999, 999 (9th Cir. 1992). Here, Mr. Ragsdale, who is the author of the document and who served as Cordis Dow's Manager of Research Electronics during the relevant time period, has testified that he was responsible for the design of the key computer hardware found in the Seratron System. *See* Gemmell Decl. ISO Mot. to Strike Exs. 1 and 13 at Ex. D (Ragsdale Decl. at ¶ 6). As such, it is beyond dispute that Mr. Ragsdale had a business duty to accurately describe the Seratron System architecture in the PRSM Specification, not only because he was supervising the development of the Seratron System, but also because the system was to be incorporated into a medical device. Since Mr. Ragsdale has testified that he authored the PRSM Specification as part of this business process, the statements contained in the document are part of a business record and are not considered hearsay.

Finally, the Court notes that Fresenius has offered a persuasive argument that the PRSM Specification falls within Rule 807's residual hearsay exception and Baxter has offered *no* persuasive arguments to the contrary. Rule 807 provides in relevant part:

A statement not specifically covered by Rule 803 or 804 but having equivalent circumstantial guarantees of trustworthiness, is not excluded by the hearsay rule, if the court determines that (A) the statement is offered as evidence of a material fact; (B) the statement is more probative on the point for which it is offered than any other evidence which the proponent can procure through reasonable efforts; and (C) the general purposes of these rules and the interests of justice will best be served by admission of the statement into evidence.

Fed. R. Evid. 807. Here, the PRSM is being offered in support of Fresenius' 35 U.S.C. § 102 affirmative defense. It is therefore unquestionably material. Further, since it is being offered as prior art, the PRSM

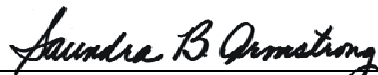
1 Specification, itself, is more probative on this issue than any other evidence that could be offered in its
2 place. Additionally, both the Federal Circuit and the United States Supreme Court have emphasized that
3 there is a significant public policy interest in resolving questions of validity when they are presented.
4 *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1354 (Fed. Cir. 2005) (citing *In Cardinal*
5 *Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100 (1993)). In light of all of these factors, and in light
6 of the fact that Baxter has failed to make any credible suggestion that the PRSM Specification has been
7 tampered with or changed in any significant respect since being drafted, the Court concludes that the
8 document is sufficiently trustworthy and that the interests of justice are best served by admitting it. *See*
9 *U.S. v. Coohey*, 11 F.3d 97, 100 (8th Cir. 1993) ("Evidence is admissible if the trial judge is satisfied,
10 after consideration of such factors as the nature of the evidence, the circumstances surrounding its
11 preservation and custody, and the likelihood that it has been tampered with, that the evidence has not
12 in all reasonable probability been changed in any significant respect."). Accordingly, Baxter's Motion
13 to Strike the PRSM Specification under the Federal Rules of Evidence is DENIED.

14 **CONCLUSION**

15 IT IS HEREBY ORDERED THAT Baxter's Motion to Strike Exhibits 1 and 13 to Fresenius'
16 Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent Nos. 5,326,476 and
17 5,744, 027 [Docket No. 498] is DENIED.

18 IT IS SO ORDERED.

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20 Dated: 5/15/06

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22 SAUNDRA BROWN ARMSTRONG
23 United States District Judge
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